

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

ASTELLAS US HOLDING, INC., et al.,

Plaintiffs,

v.

STARR INDEMNITY AND LIABILITY
COMPANY, et al.,

Defendants.

Case No. 1:17-cv-08220

Honorable Manish S. Shah

**PLAINTIFF ASTELLAS PHARMA US, INC.'S
MEMORANDUM IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT AGAINST
DEFENDANT FEDERAL INSURANCE COMPANY**

Dated: August 25, 2020

Respectfully submitted,

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

In this insurance coverage action, Astellas seeks to recover from Federal¹ a portion of a settlement that it paid to the United States to settle claims arising under the False Claims Act (“FCA”). While denying liability for any FCA violation, Astellas settled for \$102,370,890. The settlement resolved claims asserted by the Department of Justice (“DOJ”) that Astellas had violated the FCA by donating money to charitable organizations that provide co-pay assistance to Medicare beneficiaries for prescription drugs. According to DOJ, through these charitable donations, Astellas improperly caused Medicare to reimburse Medicare beneficiaries for the cost of purchasing Astellas’s cancer-fighting drug, Xtandi.

Astellas sought coverage for the cost of defending and settling DOJ’s claims under its directors and officers (“D&O”) liability insurance policies. Astellas purchased \$50 million of D&O coverage from six insurers (“Insurers”), including Federal, for the period April 1, 2015 to April 1, 2016. The Federal policy (the “Federal Policy”) is the second excess policy in that tower, with a \$10 million limit of liability, above \$10 million of underlying limits. For all purposes relevant to this motion, the Federal Policy incorporates the terms of the primary D&O liability policy (the “Primary Policy”).

There is no genuine issue of material fact as to whether the settlement payment satisfies the relevant insuring agreement in the Primary Policy (and, accordingly, the Federal Policy). Subject to certain other terms and conditions, the Federal Policy provides coverage for a “**Loss**”² arising from a **Claim** first made during the **Policy Period** . . . against the **Company** for any

¹ The other defendants in this case, Starr Indemnity and Liability Company and Beazley Insurance Company, Inc., were dismissed and terminated as parties. (ECF No. 97, Mar. 3, 2020 Minute Entry.)

² Terms in bold shall have the meanings ascribed to them in the Primary Policy.

Wrongful Act, and reported to the **Insurer** in accordance with the terms of [the Primary Policy].” Each of the requirements of this insuring agreement is satisfied.

Astellas meets the definition of **Company**, because it is a wholly owned subsidiary of Astellas US Holding, Inc. (the “Parent Company”), the entity to which the Federal Policy was issued. Under the plain terms of the Federal Policy, a wholly owned subsidiary of the Parent Company – like Astellas – falls within the definition of **Company**, making it an **Insured**.³

Astellas reported a **Claim** to the Insurers in accordance with the relevant terms of the Primary Policy. On March 11, 2016, during the **Policy Period**, Astellas gave notice to the Insurers that, on March 3, 2016, it had received a subpoena from DOJ (the “Subpoena”) as part of DOJ’s investigation into various health care offenses committed by Astellas. The Insurers, including Federal, accepted the March 11, 2016 notice only as a notice of “circumstances” that could potentially give rise to a **Claim**. Even if the Subpoena only constituted a “circumstance,” and not a **Claim**,⁴ under the terms of the Primary Policy, any future **Claim** arising out of those “circumstances” and subsequently reported to the Insurers is deemed to have been reported during the **Policy Period** (even if the **Claim** is first made after the **Policy Period**). In October 2017, the DOJ requested, in writing, that Astellas agree to toll the statute of limitations for potential Federal healthcare offenses first referenced in the Subpoena (the “DOJ Tolling Request”). Such tolling requests fall squarely within the definition of **Claim**. Because the DOJ Tolling Request “aris[es] out of, [is] based upon or attributable to” the previously noticed circumstance (the Subpoena), it is deemed under the Primary Policy to have been reported during

³ In this case, the Parent Company is also a plaintiff. But it is Astellas, not the Parent Company, that seeks coverage for the settlement payment under the Federal Policy. Astellas was the target of the DOJ’s investigation, and Astellas signed the settlement agreement and paid the amounts owed under it.

⁴ This Court agreed with Astellas that the Subpoena met the definition of **Claim**. See *Astellas US Holding, Inc. v. Starr Indem. & Liab. Co.*, No. 17-CV-8220, 2018 WL 2431969 (N.D. Ill. May 30, 2018).

the **Policy Period** *even if the DOJ Tolling Request is reported after the Policy Period* (as was the case here).

The **Claim** was for a **Wrongful Act**. The term **Wrongful Act** is defined, in relevant part, as “any actual or *alleged* breach of duty, neglect, error, misstatement, misleading statement, omission or *act* by [Astellas]” (emphasis added). It is undisputable that DOJ *alleged* that Astellas committed “acts” that violated the FCA.

At least \$51,185,445 of the settlement payment qualifies as **Loss**. This amount constitutes the non-multiplied portion of the government’s compensatory damages (with interest) that Astellas agreed to pay as part of the settlement.

Federal has asserted that the settlement is not covered because the definition of **Loss** excludes “matters which may be deemed uninsurable under applicable law.” Federal argues that because a portion of the settlement payment is designated as “restitution to the United States” in the settlement agreement, it is “uninsurable under applicable [presumably, Illinois] law.” Federal is wrong: only the restitution of *unjust gains* raises uninsurability concerns, not “restitution” paid for damages or harm suffered by the claimant. The government made no claims for the return of unjust gains, nor could it. As a matter of law, the government cannot seek the *restitution of ill-gotten gains as a remedy for an FCA* violation. Indeed, the only remedies available to the government under the FCA are multiplied compensatory “damages” and civil penalties.

Federal has also asserted that the settlement is barred by the so-called conduct exclusions. Those exclusions, however, apply only in the event of a *final non-appealable adjudication* that either (a) Astellas gained any profit or advantage that was improper or (b) Astellas committed a deliberate fraudulent act or any willful violation of law. But there has been no adjudication of any such allegations, much less a final, non-appealable one.

Accordingly, Astellas respectfully requests that this Court grant its Motion for Summary Judgment and enter judgment in its favor in the amount of \$10,000,000, plus prejudgment interest as is awardable under Illinois law.

II. STATEMENT OF UNDISPUTED FACTS

A. **The Office of the Inspector General Advises Pharmaceutical Companies that Certain Forms of Copay Assistance to Medicare Part D Beneficiaries Implicate the Anti-Kickback Statute.**

The U.S. government began subsidizing the cost of prescription drugs under Medicare Part D on January 1, 2006.⁵ (Statement of Undisputed Material Facts Pursuant to Local Rule 56.1 (“SOF”) ¶ 14.) Medicare Part D beneficiaries generally must contribute to the cost of these subsidized prescriptions through copays.⁶ (*Id.* ¶ 15.) The Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — to induce Medicare beneficiaries to purchase that company’s drugs.⁷

In a November 2005 Bulletin (the “Bulletin”), the Office of the Inspector General (“OIG”) advised that copay assistance to Medicare Part D beneficiaries paid by charitable organizations controlled by pharmaceutical manufacturers would also violate the AKS. (SOF ¶ 17.) The Bulletin further advised that donations made by pharmaceutical companies to other

⁵ Medicare Part D was authorized by Congress under the “Medicare Prescription Drug, Improvement and Modernization Act of 2003.”

⁶ A “copay” may be a “copayment,” “coinsurance,” or “deductible” that a Medicare patient pays when they obtain a prescription drug covered by Medicare Part D. (SOF ¶ 15.)

⁷ The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items reimbursable by a Federal health care program. *See* 42 U.S.C. 1320a-7b. Copay assistance constitutes remuneration that is offered to patients to induce the purchase of a specific item – a prescription drug. When the item in question is one for which payment may be made, in whole or in part, under a Federal health care program (including Medicare Part D), the AKS is implicated.

501(c)(3) organizations, not controlled by pharmaceutical manufacturers, *risks* violating the AKS in certain circumstances. (*Id.*) OIG, however, recognizing the importance to the healthcare safety net of continuing the financial assistance offered by pharmaceutical manufacturers to Medicare beneficiaries, issued guidance as to how and under what circumstances pharmaceutical manufacturers could lawfully continue making donations to “*bona fide*, independent charities unaffiliated with pharmaceutical manufacturers.” (*Id.* ¶ 17.) OIG stressed that independent charity patient assistance programs (“Independent Charity PAPs”) must decide independently how and under what circumstances to provide co-pay assistance. (*Id.* ¶ 18.)

B. Beginning in 2012, Astellas Made Donations to Independent Charitable Organizations That Provided Copay Assistance to Financially Needy Patients.

In September 2012,⁸ Astellas launched Xtandi, a drug used to treat men with metastatic castration-resistant prostate cancer (“mCRPC”).⁹ (SOF ¶¶ 19-20.) Xtandi differs from other treatments of mCRPC because it works by blocking androgen receptors, and is thus classified as an “androgen receptor inhibitor” (“ARI”). (*Id.* ¶ 21.)

Beginning in 2012, Astellas made charitable contributions to patient assistance funds run by two separate Independent Charity PAPs. (*Id.* ¶ 22.) In July 2013, after discussions with Astellas, these two Independent Charity PAPs opened two “ARI funds.” (*Id.* ¶ 23.) The ARI funds would reimburse patients (including Medicare beneficiaries) for ARI drugs used for the

⁸ Solely for purposes of this Motion for Summary Judgment (and for no other purpose), Astellas relies upon the government’s description of Astellas’s conduct in the settlement agreement, under the section titled “Covered Conduct.” By doing so, Astellas does not admit to liability or any of DOJ’s factual allegations, and Astellas reserves all of its rights to contest DOJ’s allegations in this proceeding.

⁹ mCRPC is prostate cancer that (1) no longer responds to medical or surgical treatments that lower testosterone (such as castration), and (2) has spread beyond prostate tissue. (SOF ¶ 20.)

treatment of mCRPC, but not for other mCRPC drugs.¹⁰ (*Id.* ¶ 24.) Astellas donated to the ARI funds between July 1, 2013 and December 2013. (*Id.* ¶ 25.)

C. Astellas Provided the Insurers with Timely Notice of a Subpoena Issued by the DOJ Relating to Astellas’s Payments to Independent Charity PAPs.

On March 3, 2016, DOJ issued the Subpoena. (SOF ¶ 26.) DOJ agreed to treat the Subpoena as being issued only to Astellas. (*Id.* ¶ 29.) The Subpoena demanded documents relevant to DOJ’s investigation of alleged “Federal healthcare offenses” arising out of Astellas’s charitable contributions to Independent Charity PAPs. (*Id.* ¶ 27.)

On March 11, 2016, Astellas had its broker, Marsh USA, Inc. (“Marsh”) give written notice of the Subpoena to the Insurers (the “Original Notice”). (*Id.* ¶ 30.) On March 29, 2016, the primary insurer, Starr Indemnity & Liability Company (“Starr”), provided its coverage position to Astellas. (*Id.* ¶ 31.) Starr refused to treat the Original Notice as a notice of a **Claim**, but it accepted the Original Notice as a notice of “circumstances,” contending that an investigative subpoena did not meet the Primary Policy’s definition of **Claim**. (*Id.*) Federal has adopted Starr’s position that the Subpoena was only a circumstance, not a **Claim**. (*Id.* ¶ 32.)

D. Astellas Subsequently Reported to the Insurers the DOJ’s Request to Toll the Applicable Statutes of Limitation for the Healthcare Offenses Under Investigation.

On October 19, 2017, DOJ requested that Astellas enter into a tolling agreement (the “DOJ Tolling Request.”) (SOF ¶ 33.) The tolling agreement was executed on October 26, 2017. (*Id.* ¶ 34.) The tolling agreement explained that DOJ was:

conducting a joint criminal and civil investigation of [] Astellas The conduct being investigated includes, without limitation, the possible violation by Astellas . . . of various federal criminal statutes, including, but not limited to, 42 U.S.C. § 1320a-7b (anti-kickback statute) and 18 U.S.C. § 1347 (health care fraud), and certain civil statutes, including, but not

¹⁰ The Independent Charity PAPs running those funds were the Patient Access Network Foundation (“PANF”) and the Chronic Disease Fund (“CDF”). (*Id.* ¶ 37.)

limited to, 31 U.S.C. § 3729-33 (False Claims Act) (“FCA”), in connection with Astellas’s payments to ‘501(c)(3)’ organizations that provide financial assistance to Medicare beneficiaries.”

Astellas reported the DOJ Tolling Request to the excess Insurers on November 1, 2017 (the “Second Notice”). (*Id.* ¶ 36.) The Second Notice specifically advised the Insurers that the DOJ Tolling Request constituted a **Claim**. (*Id.* ¶¶ 35-36.)

E. Settlement Discussions Ensued and, Although Their Consent Was Not Required Due to Their Coverage Denials, Astellas Requested That the Insurers Consent to the Settlement.

On or about June 20, 2018, the Assistant United States Attorney with day-to-day responsibility for the investigation told Astellas’s counsel that she was leaving DOJ at the end of the month, and that she was open to engaging in settlement discussions before her departure if Astellas wanted to settle with DOJ in the near future. (SOF ¶ 39.) Astellas agreed to such discussions. (*Id.* ¶ 40.)

On June 28, 2018, Astellas informed the Insurers (including Federal) of the above-described circumstances and the proposed terms of the settlement under discussion. (*Id.* ¶ 41.) Astellas also requested that the Insurers agree not to raise lack of consent to any settlement as a defense to coverage. (*Id.* ¶ 42.) Astellas received written agreements from all of the Insurers, except Federal, that they would waive consent to the settlement. (*Id.* ¶ 43.) Federal never responded to Astellas’s request, one way or the other. (*Id.* ¶ 44.)¹¹

Astellas and DOJ reached an agreement in principle to settle DOJ’s claims at the close of business on June 29, 2018. (SOF ¶ 45.)

F. Federal Denies Coverage for the Settlement Between Astellas and DOJ.

DOJ and Astellas executed the final written settlement agreement on April 25, 2019 (the

¹¹ In all events, since Federal had denied coverage, its settlement consent was not required.

“Settlement Agreement”). (SOF ¶ 46.) The Settlement Agreement sets forth DOJ’s allegations concerning Astellas’s conduct. (*Id.*) As described in the paragraph titled “Covered Conduct,” DOJ alleged that Astellas used Independent Charity PAPs (PANF and CDF) as conduits to funnel impermissible co-pay assistance to Xtandi patients, thereby causing Medicare beneficiaries to submit false claims for reimbursement to Medicare. (*Id.*) Astellas did not admit these allegations or liability. (*Id.*)

Astellas paid the full amount of the settlement on April 25, 2019. (SOF ¶ 48.) Astellas then demanded that Federal reimburse it for \$10 million of the settlement – the full amount of the Federal Policy limits. (*Id.* ¶ 50.) Federal has refused. (*Id.* ¶ 51.)

III. APPLICABLE POLICY LANGUAGE

The Federal Policy is an excess policy covering claims made between April 1, 2015 to April 1, 2016 (the **Policy Period**). (SOF ¶¶ 52–53.) The Federal Policy provides a \$10 million limit of liability excess of \$10 million in underlying coverage issued by five separate insurers, and a \$500,000 self-insured retention. (*Id.* ¶¶ 56–57.) Paragraph 1 of the Federal Policy, as amended by Endorsement No. 1, provides, in relevant part, as follows:

[Federal] shall provide the **Insureds** with insurance during the **Policy Period** excess of the **Underlying Limit**. Coverage hereunder shall attach only after the . . . **Insureds** . . . shall have paid in legal currency the full amount of the **Underlying Limit** for such **Policy Period**. Coverage shall then apply in conformance with the terms and conditions of the **Primary Policy**, except as otherwise provided herein.

(*Id.* ¶ 52.)

The followed Primary Policy provides coverage not just for claims brought against Astellas’s directors and officers, but also for claims brought against Astellas. Insuring Agreement 1.C. of the Primary Policy states (*Id.* ¶ 58.):

The **Insurer** shall pay on behalf of the **Company** the **Loss** arising from a **Claim** first made during the **Policy Period** . . . against the **Company** for

any **Wrongful Act**, and reported to the **Insurer** in accordance with the terms of this policy.

The Primary Policy defines **Company** as including “any **Subsidiary** of the **Parent Company**.” (*Id.* ¶ 59.) **Parent Company** is defined as Astellas US Holding, Inc. (*Id.* ¶ 60.) The term **Subsidiary** is defined, in relevant part, as “any privately-held for-profit entity . . . of which the **Parent Company** has **Management Control** . . . before the inception of the **Policy Period**.” (*Id.* ¶ 61.). “**Management Control**” means, among other things, “owning interests representing more than 50% of the voting, appointment or designation power for the selection of a majority of: the board of directors of a corporation.” (*Id.* ¶ 62.)

The term **Claim** includes, in relevant part, a “written request to toll or waive the applicable statute of limitations relating to a potential **Claim** against an **Insured** for a **Wrongful Act**.” (*Id.* ¶ 63.) The term **Wrongful Act** is defined, in relevant part, as “any actual or alleged breach of duty, neglect, error, misstatement, misleading statement, omission or act by the **Company**.” (*Id.* ¶ 64.)

Finally, the term **Loss** is broadly defined, in relevant part, to include “damages, settlements or judgments.” (*Id.* ¶ 65.) It also expressly includes the “multiplied portion of any multiple damage awards . . . but only to the extent that such damages . . . are insurable under the applicable law most favorable to the insurability of such damages.” (*Id.*)

Section 5 of the General Terms & Conditions Section of the Primary Policy, **Notice of Claim**, provides, in relevant part (*id.* ¶ 66):

[I]f during the **Policy Period** . . . an **Insured** becomes aware of any circumstances which may reasonably be expected to give rise to a **Claim** being made against an **Insured**, the **Insured** may provide written notice to the **Insurer’s** authorized agent of such circumstances. . . . If a **Claim** is subsequently made against such **Insured** and reported to the **Insurer** arising out of, based upon or attributable to the previously noticed circumstances, such **Claim** shall be considered first made at the time notice of such circumstances was provided to the **Insurer**.

IV. LEGAL STANDARDS

A. Astellas is Entitled to Summary Judgment Because There are No Genuine Issues of Material Fact.

Under Federal Rule of Civil Procedure 56, “[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “A district court should deny a motion for summary judgment only when the non-moving party presents admissible evidence that creates a genuine issue of material fact.” *Luster v. Illinois Dept. of Corr.*, 652 F.3d 726, 731 (7th Cir. 2011) (citing *United States v. 5443 Suffield Terrace*, 607 F.3d 504, 510 (7th Cir. 2010) and *Swearnigen–El v. Cook County Sheriff’s Dep’t*, 602 F.3d 852, 859 (7th Cir. 2010)).

B. Illinois Law on Insurance Contracts Governs this Dispute.

The interpretation of an insurance policy is a question of law that is appropriate for resolution through summary judgment. *Twenhafel v. State Auto Prop. & Cas. Ins. Co.*, 581 F.3d 625, 628 (7th Cir. 2009) (citing *BASF AG v. Great Am. Assurance Co.*, 522 F.3d 813, 818–19 (7th Cir. 2008)); *see also Crum & Forster Managers Corp. v. Resolution Trust Corp.*, 620 N.E.2d 1073, 1077 (1993). Illinois law governs the coverage dispute in this case because the policies were issued in Illinois, covering an Illinois insured. *See Hofeld v. Nationwide Life Ins. Co.*, 322 N.E.2d 454, 458 (1975).

Insurance policies are subject to certain of the same rules of construction applicable to other types of contracts. When construing an insurance contract, the “primary objective is to ascertain and give effect to the intent of the parties of the contract . . . if the language of the policy is susceptible to more than one meaning, it is considered ambiguous and will be construed strictly against the insurer who drafted the policy and in favor of the insured.” *Traveler’s Ins. Co. v. Eljer Mfg., Inc.*, 757 N.E.2d 481, 491–92 (2001) (internal citations omitted).

Under Illinois law, the policyholder bears the initial burden of demonstrating the existence of a claim that falls within the coverage provided by the policy. *Miner v. Bray*, 513 N.E.2d 580, 582 (1987). The insurance company then bears the burden of demonstrating that any exclusion upon which it relies clearly and unequivocally excludes coverage. *St. Michael's Orthodox Catholic Church v. Preferred Risk Mut. Ins. Co.*, 496 N.E.2d 1176, 1178 (1986); *Strzelczyk v. State Farm Mut. Automobile Ins. Co.*, 485 N.E.2d 1230 (1985), *aff'd*, 497 N.E.2d 1170 (1986). As courts have articulated insurers' burdens regarding exclusions under Illinois law: "It is well settled under the law of Illinois, as well as most other jurisdictions, that if an insurer does not intend to insure against a risk which is likely to be inherent in the business of the insured, it should specifically exclude such risk from the coverage of the policy." *Bremen State Bank v. Hartford Accident & Indem. Co.*, 427 F.2d 425, 427 (7th Cir. 1970), quoted in *Martin v. Brunzelle*, 699 F. Supp. 167, 170 (N.D. Ill. 1988).

C. Under the False Claims Act, the Government is Entitled to Seek Only Enhanced Compensatory Damages and Penalties.

The FCA imposes liability on "any person who—(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Thus, the focus of the FCA is on persons who present or induce the submission of false or fraudulent claims. The FCA broadly defines "knowingly" to include persons that "act[] in reckless disregard of the truth or falsity of the information." *Id.*

A "claim" for purposes of the FCA includes not only direct requests to the government for payment but also reimbursement requests made by the recipients of federal funds under federal benefits programs, such as Medicare. *Universal Health Servs., Inc. v. U.S.*, 136 S. Ct. 1989, 1996 (2016). Further, "a claim that includes items or services resulting from a violation of [the Anti-Kickback statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42

U.S.C. § 1320a-7b(g).

DOJ alleged that Astellas had violated the AKS by making improper donations to Independent Charity PAPs, which caused Medicare beneficiaries to present false claims to Medicare for reimbursement. (SOF ¶ 46.) DOJ’s theory in such cases was succinctly articulated by the Seventh Circuit in *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008). As explained in *Rogan*, through Medicare, the government “offers a subsidy . . . with conditions,” and *those conditions include compliance with the AKS*. *Id.* at 453. And “[w]hen the conditions are not satisfied” because of a violation of the AKS, “nothing is due.” *Id.* In short, if the conditions required for the “subsidy” are not met, the government claims that it was damaged to the full extent of the reimbursements it provided to Medicare beneficiaries. *Id.* In other words, under DOJ’s theory of FCA damages, the government does not have to prove that a pharmaceutical manufacturer’s “kickback” *in fact* increased the amount of Medicare reimbursements for that company’s drug.

Under § 3729(a) of the FCA, a violator is liable to the government for a civil penalty of not less than \$5,000 and no more than \$10,000, “*plus 3 times the amount of damages which the government sustains because of the act of that person.*” 31 U.S.C. § 3729 (emphasis added). The FCA thus imposes two types of liability. “First, the submitter of a ‘false claim’ or ‘statement’ is liable for a civil penalty, regardless of whether the submission of the claim actually causes the government any damages; even if the claim is rejected, its very submission is a basis for liability.” *U.S. ex rel. Bettis v. Odebrecht Contractors of Cal., Inc.*, 393 F.3d 1321, 1326 (D.C. Cir. 2005) (citation omitted). And second, “[t]he submitter of the claim is liable for damages that the government sustains because of the submission of the false claim.” *Id.* (citation omitted).

Thus, under § 3729(a) of the FCA, the government is only entitled to—in addition to civil

penalties—the legal remedy of **damages**. *United States ex rel. Taylor v. Gabelli*, Nov. 03-CV-8762, 2005 WL 2978921, at *7 (S.D.N.Y. Nov. 4, 2005) (“[T]he Court ascribes the common meaning of ‘damages’ in the construction of § 3729(a),” including “‘the estimated reparation in money for detriment or injury sustained[.]’”) (citing Webster’s Third New International Dictionary 571 (2002)). As one court explained, “[w]hatever Congress may have done to enhance the damages available under the FCA, the U.S. Supreme Court has consistently recognized that the purposes of the FCA in 1863 were essentially compensatory.” *U.S. ex rel. Rosales v. San Francisco Hous. Auth.*, 173 F. Supp. 2d 987, 1013 (N.D. Cal. 2001) (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551–52 (1943)). Indeed, the purpose of FCA damages is to put the government “in the same position as it would have been if the defendant’s claims had not been false.” *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1278 (D.C. Cir. 2010). ***Accordingly, the FCA does not permit the government to pursue the equitable remedy of disgorgement or the restitution of ill-gotten gains.*** *Taylor*, 2005 WL 2978921, at *7 (“Looking to the plain language of this provision and the ‘ordinary, contemporary, [and] common meaning’ of damages, the Court finds that the only allowable remedy the FCA grants [the relator] is compensatory damages and not restitution.”) (citation omitted).

V. ARGUMENT

A. **Astellas Meets the Definition of Company, and is therefore Insured Under the Federal Policy.**

Astellas is a **Subsidiary** of the **Parent Company** because the **Parent Company** had **Management Control** of Astellas. Specifically, the **Parent Company** – *i.e.*, Astellas Holding US, Inc. – owns 100% of Astellas’s common stock and had the right, at all relevant times, to select Astellas’s directors. (SOF ¶¶ 2-4.) Because the definition of **Company** in the Primary

Policy also includes **Subsidiaries** of the **Parent Company**, Astellas is insured under Insuring Agreement 1.C of the Primary Policy.

B. The DOJ Tolling Request is a Claim.

As noted above, Astellas provided the Original Notice during the **Policy Period**. (SOF ¶ 30.) Starr and Federal accepted the Original Notice as a notice of circumstances. (*Id.* ¶¶ 31 & 32.) A **Claim** “arising out of, based upon or attributable to the previously noticed circumstances” arose on October 19, 2017, when the DOJ requested, in writing, that Astellas enter into an agreement to toll the applicable statute of limitations. As this Court has held, the DOJ Tolling Request is a **Claim** because the Primary Policy defines that term as including a “written request to toll . . . the applicable statute of limitations relating to a potential **Claim** against an **Insured** for a **Wrongful Act**.” *Astellas US Holding, Inc. v. Starr Indem. & Liab. Co.*, No. 17-CV-8220, 2018 WL 2431969, at *6 (N.D. Ill. May 30, 2018) (holding that the DOJ Tolling Request’s reference to “potential violations” of statutes identified **Wrongful Acts** and therefore the DOJ Tolling Request “constitutes a ‘Claim’ under the [Starr] policy.”).¹² Further, there is no dispute that the DOJ Tolling Request “arose out of” the DOJ’s investigation of alleged federal health care offenses referenced in the March 2016 subpoena. *See id.* at *6 (finding that the DOJ Tolling Request was related to the March 2016 subpoena).

C. The DOJ Alleged a Wrongful Act.

The term **Wrongful Act** is defined as “any actual or alleged breach of duty, neglect, error, misstatement, misleading statement, omission or act by the Company.” (SOF ¶ 64.) In the Settlement Agreement, DOJ explicitly asserts that Astellas’s donations to Independent Charity

¹² The DOJ Tolling Agreement states that DOJ is “conducting a joint criminal and civil investigation” of Astellas’s “*possible* violation . . . of various federal criminal statutes,” including the FCA. (SOF ¶ 34.) And it identifies the alleged “acts or omissions” for which the applicable statute of limitations are being tolled. (*Id.*)

PAPs violated federal law:

[T]he United States has alleged and does allege: During the period July 1, 2013, through December 31, 2014, Astellas used PANF and CDF as conduits to pay the copay obligations of Medicare patients taking Xtandi. . . . As a result of the foregoing conduct, the United States contends that Astellas caused false claims to be submitted to Medicare for Xtandi prescriptions.

(*Id.* ¶ 46.) Astellas’s alleged violations of federal law for contributing to Independent Charity

PAPs thus constitute “alleged . . . act[s] by the **Company**[.]” and are **Wrongful Acts** as defined in the Primary Policy.

D. The Settlement Payment Constitutes a Loss and The “Uninsurable As a Matter of Law” Exclusion Does Not Apply.

At least \$51,185,445 of the settlement payment constitutes **Loss**, as that term is defined in the Primary Policy. **Loss** means “damages” and “settlements,” as well as “pre- and post-judgment interest.” In addition to penalties, the government’s allowable recovery under § 3729(a) of the FCA is limited to the *damages sustained by the United States* and a *multiple of those damages*.¹ USCA § 3729(a)(1); 28 CFR § 85.3(a)(9) (persons who violate the FCA are liable for “3 times the amount of *damages* which the Government sustains because of the act” giving rise to liability.”) (emphasis added).

The definition of **Loss** excludes coverage for “matters which may be deemed uninsurable under applicable law.” (SOF ¶ 65.) Federal argues that, under Illinois law, restitution of unjust gains is uninsurable. (*See* ECF 81, Federal Answer to Second Am. Compl. ¶ 33(f).)¹³ That case

¹³ *See, e.g., Local 705 v. Five Star Managers, LLC*, 735 N.E.2d 679, 682 (2000) (holding that no coverage was afforded because the defendant sustained no insurable “loss” where it simply returned the monies). And it is generally correct that “a ‘loss’ within the meaning of an insurance contract does not include the restoration of an ill-gotten gain.” *Level 3 Commc’ns, Inc. v. Fed. Ins. Co.*, 272 F.3d 908, 910 (7th Cir. 2001). Illinois law recognizes a clear distinction between the legal remedy of “damages” and the “restitution” of unjust gains. As the Illinois Supreme Court has held: “Damages differs from restitution in that damages is measured by the plaintiff’s loss; restitution is measured by the defendant’s unjust gain.” *Raintree Homes, Inc. v. Vill. of Long Grove*, 807 N.E.2d 439, 445 (2004) (quoting 1 D. Dobbs, Remedies

law, however, is inapplicable here: under the FCA, DOJ could not and did not seek from Astellas the disgorgement or “restitution” of ill-gotten gains. Disgorgement “differs—fundamentally, functionally, and definitionally—from actual damages,” *Taylor*, 2005 WL 2978921, at *13, and is “*not a remedy recoverable under the FCA*,” *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007) (emphasis added). As the court in *Taylor* explained, disgorgement “cannot be construed as compensation for ‘damages sustained’ by the Government under the False Claims Act: the Government, while perhaps harmed by defendants’ unjust enrichment, sustain[s] no actual damages or monetary losses by virtue of the defendants’ purportedly wrongful gains.” 2005 WL 2978921, at *5.

The settlement payment could arguably constitute the restoration of an unjust gain (*i.e.*, uninsurable disgorgement) only if DOJ could have “required [Astellas] to return those monies which it had no right to possess in the first place.” *Local 705*, 735 N.E.2d at 683. However, as explained, because restitution of unjust gains is not an available remedy under the FCA, the DOJ therefore neither sought, nor could it ever have sought, that remedy.¹⁴

Accordingly, whether, and to what extent, Astellas may have profited from its charitable donations was completely irrelevant both to Astellas’s liability and the amount of the government’s claimed damages. To illustrate, Astellas could have sold Xtandi for a loss, and the government’s damages claim would have been exactly the same, since its damages were

§ 3.1, at 278 (2d ed. 1993)). As explained above, the remedy for an FCA violation is measured by the government’s loss, not the violator’s “unjust gain.”

¹⁴ See also *J.P. Morgan Secs. Inc. v. Vigilant Ins. Co.*, 21 N.Y.3d 324, 336 (2013) (holding that a settlement payment labeled “disgorgement” was insurable because it did not represent the disgorgement of the insured’s illicit gains but rather the improper profits the insured’s actions allowed others to obtain).

measured exclusively *by what the government paid to third parties*—not by Astellas’s *unjust profits*, if any, from those sales.¹⁵

Federal ignores both the fact that restitution is not a remedy that is available under the FCA and that the settlement payment was based on Medicare’s actual payments to third parties, and instead focuses on labels (which it then applies incorrectly). Specifically, Federal relies on the mere fact that the Settlement Agreement designates \$50 million of the settlement amount as “restitution to the United States.” The sole purpose of designating a portion of the settlement as “restitution” in the Settlement Agreement was to identify the single damages portion of the settlement for tax purposes. Specifically, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) prohibits deductions “for any amount paid . . . to . . . a government or governmental entity in relation to . . . the investigation or inquiry by such government or entity into the potential violation of any law,” 26 U.S.C. § 162(f)(1), unless the government agrees to identify the amounts paid as “restitution . . . for damage or harm which was or may be caused by . . . the potential violation of any law.” *Id.* at § 162(f)(2)(A)(i)-(ii). Pursuant to the Tax Act, DOJ agreed to identify \$50 million of the \$100 million as “restitution.” (SOF ¶ 47.) Far from suggesting that

¹⁵ Indeed, even if the settlement payment had been based on a calculation of Astellas’s unjust profits—and it was not—that fact would be irrelevant. As explained in *Virginia Mason Medical Center v. Executive Risk Indemnification, Inc.*, No. C07-0636, 2007 WL 3473683 (W.D. Wash. Nov. 14, 2007), *aff’d*, 331 F. App’x 473 (9th Cir. 2009), in determining whether a settlement constitutes uninsurable restitution of unjust gains, a court “*must look to the award sought in the litigation*,” not how the settlement is structured. *See id.* at *7-8 (holding that because “[a] private action brought under the WCPA seeks legal damages, not restitutionary damages,” a class action settlement that required the return of undisclosed fees to patients did not constitute uninsurable restitutionary payments.). Illinois law is the same. *See Rosalind Franklin Univ. of Med. & Science v. Lexington Ins. Co.*, 2014 IL App. (1st) 113755, ¶ 76 (where “the settlement agreement disposed of all the underlying plaintiffs’ claims, including the non-disgorgement claims,” a settlement payment that equaled the amount sought to be disgorged did not constitute uninsurable disgorgement). That holding in *Rosalind Franklin University* applies *a fortiori* here because (1) DOJ sought (and could have sought) only the damages the government sustained as a result of the FCA violation, and (2) the settlement payment was not calculated based on the amount of any allegedly unjust profits earned by Astellas.

the payment was disgorgement, the “restitution” designation means the United States agreed that \$50 million of the settlement payment represents “restitution” for “damage or harm” that the United States claimed to have sustained when it made Medicare payments for Xtandi to Part D beneficiaries. Restitution *for damages* sustained by a claimant plainly is not the same thing as the restitution *of unjust gains* that are taken away from the benefitting party. And only the latter has been deemed to be uninsurable. In these circumstances, Federal cannot bear its burden to prove that the settlement payment “clearly and unequivocally” constitutes uninsurable disgorgement—which the DOJ could not and did not claim. *See St. Michael’s Orthodox Catholic Church*, 496 N.E.2d at 1178.

Accordingly, at least \$50 million of the \$100 million settlement payment (without interest) is an amount paid for “damages,” and therefore indisputably constitutes a covered **Loss** under the Primary Policy.¹⁶

E. The Underlying Policy Limits and the Limit of Liability of the Federal Policy Are Exhausted.

Because at least \$51,185,445 of the settlement payment constitutes **Loss**, Astellas has demonstrated exhaustion of (1) the retention under the Primary Policy, (2) the **Underlying Limit of Liability**, as required by Paragraph 4 of the Federal Policy (as amended by Endorsement 4), and (3) the Federal Policy’s **Limit of Liability**.

¹⁶ While all disgorgement is restitution, not all restitution is disgorgement. “Restitution” can “sometimes refer to the disgorging of something which has been taken”; but, it can also refer to “compensation for injury done.” Restitution, Black’s Law Dictionary (11th ed. 2019); *see also* “Restitution,” Oxford English Dictionary, <https://www.oed.com/view/Entry/163966?redirectedFrom=restitution#eid> (defining “restitution” as “reparation” for “hurt, loss or injury”). “Compensation for injury done” is similar to the definition of “damages,” or “[m]oney claimed by, or ordered to be paid to, a person as *compensation for loss or injury*.” Damages, Black’s Law Dictionary (11th ed. 2019) (emphasis added).

Pursuant to Paragraph 1 of the Federal Policy, Federal provides coverage when *the Insured* has paid the full amount of the **Underlying Limit** as **Loss**. The **Underlying Limit** is defined as “the amount equal to the aggregate limits of liability as set forth in Item 4 of the Declarations for all Underlying Insurance.” As shown on the Declarations page of the Federal Policy, the combined aggregate limits of the **Underlying Insurance** are \$10,000,000.¹⁷

F. The Agreement is Not Barred By the Conduct Exclusions.

Federal has the burden of demonstrating that any exclusion upon which it relies clearly and unequivocally excludes coverage. *See St. Michael’s Orthodox Catholic Church*, 496 N.E.2d at 1178. Federal relies on Exclusions 3.(a) and 3.(b) of the Primary Policy. Exclusion 3.(a) bars coverage for any “**Loss**” if a final, non-appealable adjudication in an action establishes that the Insured gained any profit or financial advantage that was improper or illegal (the “Profit or Advantage Exclusion”). (SOF ¶¶ 67–68.) Exclusion 3.(b) bars coverage for any Loss if a final, non-appealable adjudication establishes deliberate fraud or any willful violation of law. (*Id.* ¶ 68.) But there has been no such final, non-appealable adjudication because the underlying claims were settled before any such action was brought. Since there has been no final, non-appealable adjudication of any kind, much less a finding of an illegal profit or advantage, deliberate fraud or willful violation of the law, Federal cannot establish that Exclusions 3.(a) and 3.(b) bar coverage for the settlement payment.

Astellas anticipates that, in response to the simple point that there has been no adjudication establishing the pre-requisites for Exclusions 3.(a) and 3.(b), Federal will argue that

¹⁷ Federal has agreed not to contest the reasonableness of the settlement. (SOF ¶ 49.) In exchange, Astellas has agreed not to pursue coverage for Defense Costs against Federal.

it does not matter, relying upon *Level 3 Communications, Inc. v. Federal Insurance Co.*, 272 F.3d 908 (7th Cir. 2001). But *Level 3* is inapplicable.

In *Level 3*, the policyholder, Level 3, sought coverage for a settlement of a fraud claim, where the plaintiffs alleged that they had been tricked into selling their company to Level 3 for too little. In effect, Level 3 was accused of having obtained plaintiffs' company by false pretenses. Plaintiffs sought as their damages "the difference between the value of the stock at the time of trial and the price they received for the stock from Level 3." *Id.* at 910. Level 3 settled with the plaintiffs before trial, and sought coverage for the settlement payment. The policyholder argued that "[a]s long as the case is settled before entry of judgment, the insured is covered regardless of the nature of the claim against it." *Id.* at 911. In response, the Seventh Circuit stated, "That can't be right." *Id.* The Seventh Circuit held that since the only relief sought by the plaintiffs was "restitutionary in character"—in that case, the repayment of funds to which the policyholder was not entitled—the settlement of that claim could not be covered. *Id.*

Unlike the net difference between the price paid for the "winkled" stock and the true value of that stock, the relief sought by the DOJ under the FCA is not "restitutionary in character." Under the FCA, DOJ did not seek (and could not seek) to divest Astellas of the present value of the net profits, if any, that Astellas obtained as a result of its charitable donations. *Taylor*, 2005 WL 2978921, at *7 ("the only allowable remedy the FCA grants [the relator] is compensatory damages and not restitution."). The sole remedy DOJ could seek was recovery for the damages allegedly caused to the United States, which DOJ calculated by estimating the amount that Medicare paid in subsidies to Medicare beneficiaries during the time Astellas made its donations. Any alleged "profits" from those donations – i.e., the net benefit

Astellas might have received as a result of its contributions – were not any part of DOJ’s damages case.

Similarly, the FCA does not require a specific intent to defraud. A defendant also can be liable “because of ‘deliberate ignorance’ or ‘reckless disregard’ to the possibility that the submitted claim was false.” *United States v. King–Vassel*, 728 F.3d 707, 712 (7th Cir. 2013) (quoting 31 U.S.C. § 3729(a)(1)(A), (B)) (emphasis omitted). The reckless disregard required to establish the necessary scienter under the FCA is “an extension of gross negligence.” *Id.* (quoting *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997)). Accordingly, an FCA claim is not by its very “nature” a Claim for “deliberate fraud” or a “willful violation” of the law.

Accordingly, unlike in *Level 3*, the remedy for an FCA violation is neither “restitutionary in character” nor grounded in deliberate fraud or willful violations of the law. Accordingly, Exclusions 3.(a) and 3.(b) apply only in the event of a final, non-appealable adjudication. As there has been no adjudication establishing the critical elements of these exclusions, Exclusions 3.(a) and 3.(b) are inapplicable.

VI. CONCLUSION

For the foregoing reasons, Astellas respectfully requests this Court to enter summary judgment in its favor and against Federal in the amount of \$10,000,000, plus prejudgment interest as is awardable under Illinois law.

Dated: August 25, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2020, I electronically filed the foregoing **PLAINTIFF ASTELLAS PHARMA US, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT** with the Clerk of the Court using the CM/ECF system, which will effectuate service on all counsel of record.

/s/ Taylor M. Grode

Taylor M. Grode

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